



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 716

[EPA-HQ-OPPT-2011-0363; FRL-9355-9]

RIN 2070-AJ89

Health and Safety Data Reporting; Addition of Certain Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule requires manufacturers (including importers) of cadmium or cadmium compounds, including as part of an article, that have been, or are reasonably likely to be, incorporated into consumer products to report certain unpublished health and safety studies to EPA. The Interagency Testing Committee (ITC), established under section 4(e) of the Toxic Substances Control Act (TSCA) to recommend chemicals and chemical mixtures to EPA for priority testing consideration, amends the TSCA section 4(e) *Priority Testing List* through periodic reports submitted to EPA. The ITC added cadmium and cadmium compounds to the *Priority Testing List* through its 69th ITC Report.

DATES: This final rule is effective [*insert date 30 days after date of publication in the Federal Register*]. For purposes of judicial review, this final rule shall be promulgated at 1 p.m. eastern daylight/standard time on [*insert date 14 days after publication in the Federal Register*]. (See 40 CFR 23.5.)

A request to withdraw a chemical from this final rule pursuant to § 716.105(c) must be received on or before [*insert date 14 days after date of publication in the Federal Register*].

(See Unit IV. of the **SUPPLEMENTARY INFORMATION**.)

For dates for reporting requirements, see Unit III.B. of the **SUPPLEMENTARY INFORMATION**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2011-0363, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Mail:* Document Control Office (2822-1T), Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1301 Constitution Ave., NW., Washington, DC 20004

- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. ATTN: Docket ID Number EPA-HQ-OPPT-2011-0363. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2011-0363. EPA's policy is that all comments received will be included in the docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or e-mail. The [regulations.gov](http://www.regulations.gov) website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If

you send an e-mail comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Robert Jones, Chemical Control Division (7405M), Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 202-564-8161; email address: *jones.robert@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this rule if you are a manufacturer (including importer) of cadmium or cadmium compounds, including as part of an article, that have been, or are reasonably likely to be, incorporated into consumer products.

In addition to this final rule, EPA plans to propose, under a separate notice and comment rulemaking, to require the submission of TSCA section 8(d) health and safety studies from processors and distributors of cadmium or cadmium compounds, including as part of an article, that have been, or are reasonably likely to be, incorporated into consumer products to report certain unpublished health and safety studies to EPA. The proposed rule will be published in a subsequent **Federal Register** document. As provided in this rule, health and safety studies regarding cadmium or cadmium compounds in articles must be reported, with the exception of studies not subject to reporting as described at § 716.20.

While EPA has broad authority to require submission of health and safety studies on chemical substances, for the purposes of this rule EPA has limited the scope of this rule to those

chemical substances within the listed category that have been, or are reasonably likely to be, incorporated into consumer products, based on EPA's determination of what is necessary to carry out the purposes of TSCA. "Consumer product" is defined in §716.21(a)(9)(iii) of this rule to mean "any product that is sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in or around recreational areas." This definition is based on the definition of "consumer use" promulgated in 40 CFR 710.43 and the definition of "consumer product" promulgated in 40 CFR 721.3.

Potentially affected entities may include but are not limited to:

- Manufacturers of basic inorganic chemicals (except industrial gases, inorganic dyes and pigments, alkalis and chlorine, and carbon black) (NAICS code 325188).
- Manufacturers (including importers) of inorganic dyes and pigments (NAICS code 325131).
- Manufacturers of basic organic chemical products (except aromatic petrochemicals, industrial gases, synthetic organic dyes and pigments, gum and wood chemicals, cyclic crudes and intermediates, and ethyl alcohol) (NAICS code 325199).
- Establishments primarily engaged in the primary production of nonferrous metals by smelting ore and/or the primary refining of nonferrous metals by electrolytic methods or other processes (except copper and aluminum) (NAICS code 331419).
- Establishments engaging in secondary smelting, refining, and alloying of nonferrous metal (except copper and aluminum) (NAICS code 331492).
- Wholesalers of toy and hobby goods, establishments with product line 12812 (NAICS code 42392).
- Discount department stores (NAICS code 452112).

- Warehouse clubs and supercenters (NAICS code 45291).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Do I Submit CBI Information?

If you wish to claim information submitted to be CBI, it will be handled in accordance with procedures set forth in 40 CFR part 2, subpart B. If you do not assert a confidentiality claim at the time of submission, the information may be made available to the public by EPA without further notice. See 40 CFR 2.203 (Ref. 1). Do not submit this information to EPA through regulations.gov or by email. Clearly mark the part of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2 and in § 716.55. Pursuant to § 716.55, to assert a claim of confidentiality for information contained in a submitted record, you must submit two copies of the document. One copy must be complete, and you must indicate what information, if any, is claimed as confidential by marking the specific information on each page with a label such as “company confidential,” “proprietary,” or “trade secret” and briefly state the basis of the claim. The second copy must be complete, except that all the information claimed as CBI in the first copy must be deleted. The second copy will be placed in the public docket.

Failure to furnish a second copy when information is claimed as CBI in the first copy will be considered a presumptive waiver of confidentiality. EPA will notify the respondent by certified mail that a finding of a presumptive waiver of the claim of confidentiality has been made. The respondent will be given 30 days from the date of receipt of notification to submit the required second copy. If the respondent fails to submit the second copy within the 30 days, EPA will place the first copy in the docket.

II. Background

A. Why is the Agency Taking this Action?

EPA has classified cadmium as a Group B1, probable human carcinogen (Ref. 2). Further, EPA has determined acute (short-term) effects of cadmium in humans through inhalation exposure consisting mainly of effects on the lung, such as pulmonary irritation. Chronic (long-term) inhalation or oral exposure to cadmium leads to a build-up of cadmium in the kidneys which can cause kidney disease. Cadmium has been shown to be a developmental toxicant in animals, resulting in fetal malformations and other effects, but no conclusive evidence exists in humans. Animal studies have demonstrated an increase in lung cancer from long-term inhalation exposure to cadmium (Refs. 2-4). Due to the potential health effects of exposure to cadmium or cadmium compounds, EPA and the Consumer Product Safety Commission (CPSC) are concerned about the possible presence and bioavailability of cadmium or cadmium compounds in consumer products generally and especially those consumer products used by or around children (Ref. 5).

B. What Action is the Agency Taking?

EPA is issuing a final TSCA section 8(d) rule under procedures in the Health and Safety Data Reporting rule, 40 CFR part 716, to require manufacturers (including importers) of

cadmium or cadmium compounds, including as part of an article, that have been, or are reasonably likely to be, incorporated into consumer products to submit certain unpublished health and safety studies to EPA.

EPA has reviewed CPSC's recalls of cadmium-contaminated children's products. Most of the recalled products were produced abroad and imported from other countries (Ref. 6). Based in part on this information, EPA expects to capture health and safety studies conducted by importers of such products through this final rule. These parties are located primarily in the United States and may be subject to CPSC certification requirements and, depending on the product, may be conducting testing using Standard Consumer Safety Specification for Toy Safety, ASTM International (ASTM) F-963 (Ref. 7).

The regulatory text of this final rule lists the category cadmium and cadmium compounds. The regulatory text also lists the data reporting requirements imposed by this amendment to the TSCA section 8(d) model rule.

C. What is the Agency's Authority?

Section 8(d) of TSCA authorizes EPA to require "any person who manufactures, processes, or distributes in commerce or who proposes to manufacture, process, or distribute in commerce, any chemical substance or mixture" to submit lists of health and safety studies conducted or initiated by or for such person with respect to such substance or mixture at any time, known to such person, or reasonably ascertainable by such person; and copies of any study contained on a list submitted pursuant to section (8)(d)(1) of TSCA or otherwise known by such person. Under TSCA section 3(7), import is included in the definition of "manufacture."

The term health and safety study should be interpreted broadly and is defined in § 716.3.

Since the TSCA section 8(d) model rule is codified in 40 CFR part 716, EPA uses this TSCA section 8(d) model rule to quickly gather information on chemical substances. The TSCA section 8(d) model rule requires past, current, and prospective manufacturers (including importers) and (if specified by EPA in a particular rule or notice under TSCA section 8(d)) processors to submit to EPA copies and lists of health and safety studies on the listed chemical substances that they manufacture, import, or process. These studies provide EPA with useful information and have provided significant support for EPA's decisionmaking under TSCA sections 4, 5, 6, 8, and 9.

The TSCA section 8(d) model rule provides for the addition of TSCA section 4(e) *Priority Testing List* chemical substances or categories of chemical substances. EPA is amending the TSCA section 8(d) model rule by adding the recommended category of chemical substances consistent with § 716.105(b) and (c). In doing so, EPA must provide a 14-day period, which starts upon publication of the amendments to the TSCA section 8(d) model rule in the **Federal Register**, for persons to submit information showing why a chemical substance, mixture, or category of chemical substances should be withdrawn from the amendment. The amendment adding these chemical substances to the TSCA section 8(d) model rule is effective 30 days after date of publication in the **Federal Register**. If the EPA Administrator withdraws a chemical substance from the amendment, then no later than 30 days after the date of publication of the amendment in the **Federal Register**, a **Federal Register** document announcing this decision will publish.

D. Why is this Action Being Issued as a Final Rule?

EPA is publishing this action as a final rule pursuant to the procedures set forth in

§ 716.105(b) and (c). EPA finds that there is “good cause” under the Administrative Procedure Act (APA) (5 U.S.C. 553(b)(3)(B)) to make these amendments without prior notice and comment. EPA believes notice and an opportunity for comment on this action are unnecessary. TSCA directs the ITC to add chemical substances to the *Priority Testing List* for which EPA should give priority consideration. EPA also lacks the authority to remove a chemical substance from the *Priority Testing List* once it has been added by the ITC. As explained earlier in this preamble, pursuant to § 716.105(b) and (c), once the ITC adds a chemical substance to the *Priority Testing List*, EPA adds that chemical substance to the list of chemical substances subject to the TSCA section 8(d) model rule reporting requirements, unless the ITC designated and recommended more than 50 chemical substances or categories of chemical substances in a calendar year or EPA withdraws the chemical substance from the TSCA section 8(d) model rule for good cause. EPA promulgated this procedure in 1985 after having solicited public comment on the need for and mechanics of this procedure (Ref. 8). Because that rule established the procedure for adding ITC chemical substances to the TSCA section 8(d) model rule, it is unnecessary to request comment on the procedure in this action. Finally, § 716.105(b) and (c) do provide EPA with the discretion to withdraw a chemical substance from the TSCA section 8(d) model rule for good cause, including if a party submits to EPA information showing good cause that a chemical substance should be removed from the TSCA section 8(d) model rule.

III. Final Rule

A. What Chemicals are to be Added?

EPA is adding the category of cadmium and cadmium compounds to the TSCA section 8(d) model rule as requested by the ITC in the 69th ITC Report (Ref. 9). This final rule requires manufacturers (including importers) of cadmium or cadmium compounds, including as part of an

article, that have been, or are reasonably likely to be, incorporated into consumer products to report certain unpublished health and safety studies to EPA.

B. What are the General Reporting Requirements and Deadlines?

This final rule, issued pursuant to TSCA section 8(d) and its regulations, requires manufacturers (including importers) of cadmium or cadmium compounds, including as part of an article, that have been, or are reasonably likely to be, incorporated into consumer products to report certain unpublished health and safety studies to EPA. Listed in this unit are the reporting requirements for the chemical substances being added by this action to the TSCA section 8(d) model rule.

The following types of persons need to report:

1. Persons who, in the 10 years preceding the date a chemical substance is listed at § 716.120, either have proposed to manufacture or import or have manufactured or imported the listed substance must submit to EPA, during the 60-day reporting period specified in § 716.65 and according to the reporting schedule set forth at § 716.60, a copy of each health and safety study which is in their possession at the time the chemical substance is listed.

2. Persons who, at the time the chemical substance is listed, propose to manufacture or import, or are manufacturing or importing the listed chemical substance must submit to EPA during the 60-day reporting period specified in § 716.65 and according to the reporting schedule set forth at § 716.60:

- i. A copy of each health and safety study which is in their possession at the time the chemical substance is listed.

- ii. A list of the health and safety studies known to them but not in their possession at the time the chemical substance is listed.

iii. A list of the health and safety studies that are ongoing at the time the chemical substance is listed and are being conducted by or for them.

iv. A list of the health and safety studies that are initiated after the date the chemical substance is listed and will be conducted by or for them.

v. A list of unpublished studies which have been sent to a Federal agency with no claims of confidentiality or copies of each such study.

vi. A copy of each health and safety study that was previously listed as ongoing or subsequently initiated (i.e., listed in accordance with reporting requirements described at Unit III.B.2.iii. and iv. respectively) when complete--regardless of completion date.

3. Persons who, after the time the substance is listed, propose to manufacture or import the listed chemical substance must submit to EPA during the reporting period specified in § 716.65 and according to the reporting schedule set forth at § 716.60:

i. A copy of each health and safety study which is in their possession at the time they propose to manufacture or import the listed chemical substance.

ii. A list of the health and safety studies known to them but not in their possession at the time they propose to manufacture or import the listed chemical substance.

iii. A list of the health and safety studies that are ongoing at the time they propose to manufacture or import the listed chemical substance, and are being conducted by or for them.

iv. A list of the health and safety studies that are initiated after the time they propose to manufacture or import the listed chemical substance, and will be conducted by or for them.

v. A list of unpublished studies which have been sent to a Federal agency with no claims of confidentiality or copies of each such study.

vi. A copy of each health and safety study that was previously listed as ongoing or subsequently initiated (i.e., listed in accordance with reporting requirements described in Unit III.B.3.iii. and iv. respectively) when complete--regardless of the completion date.

Generally, the reporting described in Unit III.B. is required by *[insert date 90 days after date of publication in the **Federal Register**]*. Any person who manufactures or imports, or who proposes to manufacture or import, the listed chemical substance as described in Unit III.B. from *[insert date 30 days after date of publication in the **Federal Register**]* to *[insert date 90 days after date of publication in the **Federal Register**]* must inform EPA by submitting a list of any studies initiated during the period from *[insert date 30 days after date of publication in the **Federal Register**]* to *[insert date 90 days after date of publication in the **Federal Register**]* within 30 days of their initiation, but in no case later than *[insert date 120 days after date of publication in the **Federal Register**]*. In addition, if any such person has submitted lists of studies that were ongoing or initiated during the period from *[insert date 30 days after date of publication in the **Federal Register**]* to *[insert date 90 days after date of publication in the **Federal Register**]* to EPA, such person must submit a copy of each study within 30 days after its completion, regardless of the study's completion date. See §§ 716.60 and 716.65.

Detailed requirements for reporting unpublished health and safety studies are published in 40 CFR part 716. Also found there are explanations of the reporting exemptions.

C. What are the Chemical Specific Reporting Requirements?

Pursuant to § 716.20(b)(5), the types of health, and/or environmental effects studies that need to be reported and the chemical substance grade/purity requirements that need to be met or exceeded in individual studies for cadmium and cadmium compounds are as follows:

1. For the category “cadmium and cadmium compounds” (defined as compounds including any unique chemical substance that contains cadmium as part of that chemical’s structure), reporting would extend to all unpublished health and safety studies generally reportable under §§ 716.10 and 716.20, for example but not limited to those that:

i. Relate to the cadmium content (either from cadmium or cadmium compounds) of consumer products (including the specific cadmium compound (defined in Unit III.A.) used in the products such as surface coatings and filler), data related to the product formulations, and function of the cadmium (e.g., stabilizer, colorant, etc.) in the products.

ii. Relate to the assessment of consumer exposure to cadmium from such products (including studies of bioavailability, description of the consumer use (e.g., paints used on plastics), physical form of the product containing cadmium, method of consumer product application (e.g., spray applied, etc.), number of potentially exposed consumers).

iii. Include data on cadmium migration from products (e.g., conducted using acid extraction or saline solution tests).

iv. Include bio-monitoring data on cadmium presence in tissues.

v. Focus on route, duration, and frequency of exposure to cadmium in products.

vi. Provide toxicity data on cadmium or cadmium compounds including *in vitro*, *in vivo*, epidemiological, computational, or other studies on effects of exposure to or use of the cadmium-containing product, material, or component.

vii. Discuss the function or use of cadmium or cadmium compounds in a product, material or component including typical concentration.

viii. Include data conducted in compliance with ASTM certification standards and studies focusing on the effects of the cadmium or cadmium compounds in consumer products on the health and safety of children.

2. With regard to purity, studies showing any measurable content of cadmium or cadmium compounds must be submitted.

D. What are the Economic Implications of this Action?

EPA's economic analysis for the addition of cadmium and cadmium compounds to the Health and Safety Data Reporting rule is entitled "TSCA Section 8(d): Economic Impact Analysis for the Addition of Manufacturers and Importers of Consumer Products Containing Cadmium and Cadmium Compounds from the Sixty-Ninth Report of the TSCA Interagency Testing Committee to the Health and Safety Data Reporting Rule" (Ref. 10), and can be found in the docket for this rule.

EPA has estimated that 1,384 firms are subject to the rule and that 28 firms will have relevant studies to submit to EPA. EPA believes firms that are subject to the rule will need to perform various activities in order to comply with its requirements. The estimated cost of this TSCA section 8(d) rule to firms is approximately \$481,000.

The estimated cost of this TSCA section 8(d) rule to the Federal Government is approximately the time of 300 hours. That will amount to a cost to the Federal Government of approximately \$23,500.

IV. Requesting a Chemical Substance be Withdrawn from the Final Rule

As specified in § 716.105(c), EPA may remove a chemical substance or category of chemical substances from this final rule for good cause prior to the effective date of this final rule. Any person who believes that the reporting required by this final rule is not warranted for a

chemical substance, or the category of chemical substances listed in this final rule may submit to EPA reasons for that belief. You must submit your request to EPA on or before [*insert date 14 days after date of publication in the **Federal Register***] and in accordance with the instructions provided in § 716.105(c) and (d), which are briefly summarized here. In addition, to ensure proper receipt by EPA, you should identify docket ID number EPA-HQ-OPPT-2011-0363 on your request and must submit that request in accordance with the instructions in § 716.105(c) and (d). If the Assistant Administrator, Office of Chemical Safety and Pollution Prevention, withdraws a chemical substance or the category of chemical substances from this TSCA section 8(d) amendment, in accordance with § 716.105(c), a **Federal Register** document announcing this decision will be published no later than [*insert date 30 days after date of publication in the **Federal Register***].

V. References

The docket for this final rule has been established under docket ID number EPA-HQ-OPPT-2011-0363. The docket is available for review as specified in **ADDRESSES**. The following is a listing of the documents referenced in this preamble that have been placed in the docket for this final rule:

1. EPA. Requests for Information; Confidentiality of Business Information; Final Rule. **Federal Register** (41 FR 36902, September 1, 1976).
2. EPA. Integrated Risk Information System. Cadmium (CASRN 7440-43-9) IRIS Summary. June 1992. Available online at: <http://www.epa.gov/iris/subst/0141.htm>.
3. Agency for Toxic Substances and Disease Registry (ATSDR), U.S. Department of Health and Human Services (HHS). ATSDR Toxicological Profile for Cadmium (Draft).

September 2008. Available online at:

<http://www.atsdr.cdc.gov/toxprofiles/tp.asp?id=48&tid=15>.

4. Technology Transfer Network Air Toxics Web Site, Cadmium Compounds (A).

January 2000. Available online at: *<http://epa.gov/ttn/atw/hlthef/cadmium.html>.*

5. ITC. Sixty-Eighth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency; Receipt of Report and Request for Comments; Notice. **Federal Register** (76 FR 46174, August 1, 2011) (FRL-8879-3). Available online at: *<http://www.gpo.gov/fdsys/pkg/FR-2011-08-01/pdf/2011-19414.pdf>.*

6. CPSC. Recalls and Product Safety News. Available online at:

<http://www.cpsc.gov/cgi-bin/haz.aspx> and select “Cadmium.”

7. Standard Consumer Safety Specification for Toy Safety, ASTM F-963. Available online at: *<http://www.astm.org/Standards/F963.htm>* and also available online at:

<http://www.regulations.gov> in docket ID number EPA-HQ-OPPT-2011-0363.

8. EPA. Chemical Information Rules; Additional Automatic Reporting; Final Rule.

Federal Register (50 FR 34809, August 28, 1985).

9. ITC. Sixty-Ninth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency; Receipt of Report and Request for Comments; Notice. **Federal Register** (77 FR 30856, May 23, 2012) (FRL-9346-3). Available online at: *<http://www.gpo.gov/fdsys/pkg/FR-2012-05-23/pdf/2012-12493.pdf>.*

10. EPA. TSCA Section 8(d): Economic Impact Analysis for the Addition of Manufacturers and Importers of Consumer Products Containing Cadmium and Cadmium Compounds from the Sixty-Ninth Report of the TSCA Interagency Testing Committee to the Health and Safety Data Reporting Rule. May 14, 2012.

VI. Statutory and Executive Order Reviews

A. Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), entitled “Regulatory Planning and Review,” this action is not a “significant regulatory action” and was therefore not reviewed by the Office of Management and Budget (OMB) under Executive Orders 12866 and 13563, entitled “Improving Regulation and Regulatory Review” (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act

The information collection requirements contained in TSCA section 8(d) model rules have already been approved by OMB under the provisions of the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, and OMB control number 2070-0004 (EPA ICR No. 0575). The collection activities in this final rule are captured by the existing approval and do not require additional review and/or approval by OMB.

EPA estimates that the information collection activities related to health and safety data reporting for the category of cadmium and cadmium compounds in this final rule will result in a total public reporting burden of 7,019 hours. Of that total, an estimated 2,768 hours are estimated to be spent performing an initial review of the final rule. The remaining hours are associated with the actual required reporting activities (Ref. 10). As defined by PRA and 5 CFR 1320.3(b), “burden” means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to: Review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train

personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Under PRA, an agency may not conduct or sponsor, and a person is not required to respond to, an information collection request unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, including its regulations implementing TSCA section 8(d) at 40 CFR part 716, are listed in the table in 40 CFR part 9 and included on the related collection instrument. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320.

C. Regulatory Flexibility Act

This final rule is not subject to the Regulatory Flexibility Act (RFA), which generally requires an agency to prepare a regulatory flexibility analysis for any rule that will have a significant economic impact on a substantial number of small entities. RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA) or any other statute. This rule is not subject to notice and comment requirements under the APA or any other statute because although the rule is subject to the APA, the Agency has invoked the "good cause" exemption under 5 U.S.C. 553(b)(3)(B), therefore it is not subject to the notice and comment requirement.

D. Unfunded Mandates Reform Act

Pursuant to Title II of the Unfunded Mandates Reform Act, 2 U.S.C. 1531-1538, EPA has determined that this final rule does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. In addition, EPA has determined that this final rule will not

significantly or uniquely affect small governments. Accordingly, the final rule is not subject to the requirements of UMRA sections 202, 203, 204, or 205.

E. Federalism

Under Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), EPA has determined that this final rule does not have federalism implications because it will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in the Executive Order. The rule establishes reporting requirements that apply to manufacturers (including importers) of a category of cadmium and cadmium compounds. The requirements of this final rule are not expected to apply to States and localities and would not affect State and local governments.

F. Indian Tribal Governments

This action will not have tribal implications as specified in Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000). EPA has determined that this final rule will not have tribal implications because it will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in the Executive Order. EPA has no information to indicate that any tribal government manufactures or imports the chemical substances covered by this action.

G. Protection of Children

This action is not subject to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because this

action is not an economically significant regulatory action as defined by Executive Order 12866. However, cadmium and cadmium compounds are used in toys that are intended for use by children, and thus presents a disproportionate risk to children. The agency adequately considered children's health issues during rule development.

H. Effect on Energy Supply, Distribution, or Use

This action is not a "significant energy action" as defined in Executive Order 13211, entitled "Actions Concerning Regulations that Significantly Affect Energy Supply Distribution" (66 FR 28355, May 22, 2001), because this action is not an economically significant regulatory action as defined by Executive Order 12866, and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

I. Technical Standards

Because this action will not involve any technical standards, section 12(d) of the National Technology Transfer and Advancement Act, 15 U.S.C. 272 note, does not apply to this action.

J. Environmental Justice

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994). This action is expected to have a positive impact on children in low-income and minority communities by increasing the amount of cadmium health and safety data available to EPA and consumers.

VII. Congressional Review Act

Pursuant to the Congressional Review Act, 5 U.S.C. 801 *et seq.*, EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of

Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 716

Environmental protection, Chemicals, Hazardous substances, Health and safety studies,
Reporting and recordkeeping requirements.

Dated: November 20, 2012.

Wendy C. Hamnett,

Director, Office of Pollution Prevention and Toxics.

Therefore, 40 CFR chapter I is amended as follows:

PART 716—[AMENDED]

1. The authority citation for part 716 continues to read as follows:

Authority: 15 U.S.C. 2607(d).

2. In § 716.21, add new paragraph (a)(9) to read as follows:

§ 716.21 Chemical specific reporting requirements.

(a) * * *

(9) (i) Reporting requirements for the category “cadmium and cadmium compounds” apply only to persons that manufacture (including import) cadmium or cadmium compounds that have been, or are reasonably likely to be, incorporated into consumer products.

(A) All unpublished health and safety studies generally reportable under 40 CFR 716.10 and 716.20 must be reported.

(B) [Reserved]

(ii) With regard to purity, studies showing any measurable content of cadmium or cadmium compounds in such products must be reported.

(iii) For the purposes of this paragraph (a)(9), *consumer product* means any product that is sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in or around recreational areas.

* * * * *

3. In § 716.120, add, before the entry “Chlorinated benzenes, mono-, di-, tri-, tetra-, and penta-,” the category “Cadmium and cadmium compounds” and its entry in alphabetical order to the table in paragraph (c) to read as follows:

§ 716.120 Substances and listed mixtures to which this subpart applies.

* * * *

(c) * *

Category	CAS No. (example s for category)	Special exemptions	Effective date	Sunset date
* * *	*	*	*	*
Cadmium and cadmium compounds (any unique chemical substance that contains cadmium as part of that chemical's structure)			<i>[Insert date 30 days after date of publication in the Federal Register]</i>	<i>[Insert date 90 days after date of publication in the Federal Register]</i>
Manufacturers (including importers)	-----	§ 716.21(a)(9)		
* * *	*	*	*	*

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